

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

1-73. (cancelled)

74. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 73, ~~characterized in that~~ 95, wherein the concentration of active principle is between 50 and 100%.

75. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 73, ~~characterized in that~~ it 95, wherein said delayed-release formulation has a thin and elongated form with a diameter not exceeding 3mm.

76. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 75, ~~characterized by~~ wherein said delayed-release formulation has a diameter not exceeding 2 mm.

77. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 75, ~~characterized by~~ wherein said delayed-release formulation has a diameter of the order of 0.1 mm.

78. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 73, ~~characterized by~~ 98, wherein said delayed-release formulation has a minimum

length/diameter ratio of 10.

79. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 73, ~~characterized in that~~ it wherein said delayed-release formulation contains an active principle of peptide or protein nature.

80. (currently amended) ~~Solid~~ A solid delayed-release formulation for parenteral administration through an invasive device delivering said formulation in a body comprising a homogeneous mixture of an active principle wherein the active principle is a proteic or peptidic active principle other than insulin, in ~~the~~ a non-dispersed state forming a continuous phase of which at least one part is in direct contact with the exchange surface of the formulation and of the exterior biological medium, and of a biodegradable biocompatible excipient, in which the quantity of active principle is at least 50% by weight with respect to the total weight of the formulation, and having a release profile which is independent of the composition of the excipient, of the molecular weight of the excipient or of the active principle/excipient weight ratio, the release profile being ~~essentially exclusively~~ substantially dependent on the total quantity of active principle present in the formulation.

81. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 80, ~~characterized in that~~ wherein the biodegradable biocompatible excipient is a polymer or copolymer of lactic and/or glycolic acid or a mixture of polymers

and/or copolymers of lactic and/or glycolic acid.

82. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 81, ~~characterized in that~~ wherein the said biodegradable biocompatible polymer is a copolymer of lactic acid and glycolic acid (PLGA).

83. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 80, ~~characterized in that~~ wherein the said biodegradable biocompatible polymer is a copolymer of lactic and glycolic acid having an intrinsic viscosity in chloroform at 1 g per 100 ml of greater than 0.6 dl/g.

84. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 82, ~~characterized in that~~ wherein the copolymer of lactic acid and glycolic acid is of hydrophilic nature.

85. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 80, ~~characterized in that,~~ wherein when ~~it~~ said delayed-release formulation is placed in vitro in a physiological liquid medium, ~~it~~ said delayed-release formulation liberates almost the whole of the active principle in less than a week, and, when ~~it~~ said delayed-release formulation is placed in vivo subcutaneously or intramuscularly, has a release of active principle over a period substantially greater than one week.

86. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 80, ~~characterized in that~~ it wherein said delayed-release formulation comprises a mixture of the active principle and the excipient which is homogenous at all points.

87. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 80, ~~characterized in that~~ wherein the release takes place in a single diffusion phase of the active principle.

88. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 80, ~~characterized in that~~ wherein the active principle represents at least 51%, ~~advantageously at least 60%, preferably at least 70% and up to 99.999%~~ by weight with respect to the total weight of the formulation, the excipient representing less than 50%, ~~preferably less than 49%, and more advantageously less than 30%~~ by weight with respect to the total weight of the formulation.

89. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 80, ~~characterized in that~~ wherein the active principle is selected from the group consisting of a peptide, a peptide analogue, [[or]] a protein, especially LHRH or Luteinizing Hormone-Releasing Factor (LHRH), an analogue of LHRH, especially Triptoreline and triptorelin.

90. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 80, ~~characterized in that~~

~~it~~ wherein said delayed-release formulation is in cylindrical form and has a diameter less than or equal to 3 mm, ~~preferably less than 1 mm.~~

91. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 80, adapted for injection by the intramuscular or subcutaneous route.

92. (currently amended) ~~Delayed-release~~ The delayed-release formulation according to Claim 80, ~~characterized in that~~ it wherein said delayed-release formulation is in the form of an implant.

93. (currently amended) ~~Process~~ A process for preparation of a delayed-release formulation according to Claim 80, comprising the steps ~~consisting in:~~

- producing a homogeneous mixture of the active principle and the excipient, containing at least 50% of active principle;
- compacting the said mixture; and
- extruding the said compacted mixture in the molten state.

94. (currently amended) ~~Process~~ A process for preparation of a formulation according to Claim 80, comprising the steps ~~consisting in:~~

- producing a homogeneous mixture of the active principle and the excipient, containing at least 50% of active principle;

- subjecting the homogeneous mixture of a high compression;

- grinding the compressed articles obtained; and
- putting into a form suitable for administration.

95. (new) A solid or semi-solid delayed-release formulation, adapted for implantation in a deposit site of a body via an invasive device containing at least one active principle and a biodegradable excipient, wherein the excipient is a polylactide-glycolide (PLGA) copolymer, the active principle is a proteic or peptidic active principle not being insulin, wherein the concentration of active principle is between 40 and 100%, and wherein the excipient does not form a matrix containing the active principle, whereby the release profile of the active principle is substantially constant and the duration of release is substantially greater *in vivo* than in a physiological aqueous medium *in vitro*.

96. (new) The delayed-release formulation according to claim 95, wherein the amount of active principle is limited for a local pharmaceutical activity on said deposit site.

97. (new) The delayed-release formulation according to claim 95, wherein said delayed-release formulation is a non-dispersed solid or semi-solid formulation.

98. (new) The delayed-release formulation according to claim 95, wherein said delayed-release formulation is a solid or a semi-solid dispersed formulation.

99. (new) A solid delayed-release formulation for parenteral administration through an invasive device delivering said formulation in a body comprising a homogeneous mixture of an active principle wherein the active principle selected from the group consisting of triptorelin acetate, lanreotide acetate, triptorelin, goserelin, leuprorelin, buserelin, triptorelin salts, goserelin salts, leuprorelin salts, buserelin salts, a compound having an LH-RH activity, an LH-RH antagonist, a GPIIb/IIIa antagonist, a compound having an activity similar to a GPIIb/IIIa antagonist, erythropoietin or one of its analogues, an erythropoietin analogue, an  $\alpha$  interferon,  $\beta$  interferon,  $\gamma$  interferon, somatostatin, a somatostatin derivative or analogue, a growth hormone, a growth hormone release factor, an epidermal growth factor, a melanocyte-stimulating hormone, a thyrotropin release hormone, a salt of a thyrotropin release hormone or one of its salts or derivatives, a thyroid-stimulating hormone (TSH), a luteinizing, a follicle-stimulating hormone (FSH), insulin, a parathyroid hormone or one of its derivatives, a hydrochloride of lysozyme, human PTH hormone, vasopressin or one of its derivatives, oxytocin, calcitonin, a calcitonin derivative, glucagon, gastrin, secretin, pancreozymin, cholecystokinin, angiotensin, human placenta lactogen, human chorionic gonadotropin, enkephalin, colony-stimulating factor, and interleukin, an enkephalin derivative, kyotorphin, an interleukin, tuftsin, thymopoietin, thymosthymine, thymic humoral

factor, thymic serum factor, a derivative of thymic serum factor, thymosin, thymic factor X, tumor necrosis factor, motilin, bombesin, a bombesin derivative, prolactin, neurotensin, dynorphin, careulein, substance P, urokinase, asparaginase, bradykinin, kallikren, nerve growth factor, a blood coagulation factor, polymixin B, colistin, gramycin, bacitracin, a peptide stimulating protein synthesis, an antagonist of endothelin, a vaso-active intestinal polypeptide, adrenocorticotrophic hormone, a platelet-derived growth factor, a bone morphogenic protein, and a gastric inhibitor polypeptide, in a non-dispersed state forming a continuous phase of which at least one part is in direct contact with the exchange surface of the formulation and of the exterior biological medium, and of a biodegradable biocompatible excipient, in which the quantity of active principle is at least 50% by weight with respect to the total weight of the formulation, and having a release profile which is independent of the composition of the excipient, of the molecular weight of the excipient or of the active principle/excipient weight ratio, the release profile being substantially dependent on the total quantity of active principle present in the formulation.

100. (new) A solid or semi-solid delayed-release formulation, adapted for implantation in a deposit site of a body via an invasive device containing at least one active principle and a biodegradable excipient, wherein the excipient is a polylactide-glycolide (PLGA) copolymer, the active principle



selected from the group consisting of triptorelin acetate, lanreotide acetate, triptorelin, gosserelein, leuprorelin, buserelin, triptorelin salts, gosserelein salts, leuprorelin salts, buserelin salts, a compound having an LH-RH activity, an LH-RH antagonist, a GPIIb/IIIa antagonist, a compound having an activity similar to a GPIIb/IIIa antagonist, erythropoietin or one of its analogues, an erythropoietin analogue, an  $\alpha$  interferon,  $\beta$  interferon,  $\gamma$  interferon, somatostatin, a somatostatin derivative or analogue, a growth hormone, a growth hormone release factor, an epidermal growth factor, a melanocyte-stimulating hormone, a thyrotropin release hormone, a salt of a thyrotropin release hormone or one of its salts or derivatives, a thyroid-stimulating hormone (TSH), a luteinizing, a follicle-stimulating hormone (FSH), insulin, a parathyroid hormone or one of its derivatives, a hydrochloride of lysozyme, human PTH hormone, vasopressin or one of its derivatives, oxytocin, calcitonin, a calcitonin derivative, glucagon, gastrin, secretin, pancreozymin, cholecystokinin, angiotensin, human placenta lactogen, human chorionic gonadotropin, enkephalin, colony-stimulating factor, and interleukin, an enkephalin derivative, kyotorphin, an interleukin, tuftsin, thymopoietin, thymosthymine, thymic humoral factor, thymic serum factor, a derivative of thymic serum factor, thymosin, thymic factor X, tumor necrosis factor, motilin, bombesin, a bombesin derivative, prolactin, neurotensin, dynorphin, careulein, substance P, urokinase,

asparaginase, bradykinin, kallikren, nerve growth factor, a blood coagulation factor, polymixin B, colistin, gramicin, bacitracin, a peptide stimulating protein synthesis, an antagonist of endothelin, a vaso-active intestinal polypeptide, adrenocorticotrophic hormone, a platelet-derived growth factor, a bone morphogenic protein, and a gastric inhibitor polypeptide, wherein the concentration of active principle is between 40 and 100%, and wherein the excipient does not form a matrix containing the active principle, whereby the release profile of the active principle is substantially constant and the duration of release is substantially greater *in vivo* than in a physiological aqueous medium *in vitro*.